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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/024,857	12/18/2001	Matt Wallach	005306.P069	6823
7590 08/16/2004  R. Alan Burnett  BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP  Seventh Floor 12400 Wilshire Boulevard  Los Angeles, CA 90025-1026			EXAMINER	
			PARDO, THUY N	
			ART UNIT	PAPER NUMBER
			2175	
			DATE MAILED: 08/16/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

·		Application No.	Applicant(s)				
Office Action Summary		10/024,857	WALLACH ET AL.				
		Examiner	Art Unit				
		Thuy Pardo	2175				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)⊠	Responsive to communication(s) filed on <i>February 08, 2002</i> .						
	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositi	ion of Claims						
5)□ 6)⊠ 7)□	4)						
Applicati	on Papers						
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on 18 December 2001 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>							
Priority u	ınder 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment	• •						
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) X Interview Summary ( Paper No(s)/Mail Da					
3) 🔲 Inforn	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date		atent Application (PTO-152)				

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## DETAILED ACTION

- 1. Because Examiner fails to consider the Preliminary Amendment filed on February 08, 2002, the previous Office Action, regarding to the original application filed on December 18, 2001, has been withdrawn.
- 1. Applicant's Preliminary Amendment filed on February 08, 2002 has been reviewed.

  Claim 1 has been amended and claims 2-24 have been added.
- 2. Claim 1-24 are presented for examination.

#### Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103 that form the basis for the rejections under this section made in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thangaraj et al. (Hereinafter "Thangaraj") US Patent Application No. 2003/0208378, in view of De Vries et al. (Hereinafter "De Vries") US Patent Application No. 2004/0006553.

As to claim 1, Thangaraj teaches the invention substantially as claimed, comprising:

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enabling an administrator to define a plurality of clinical trial parameters through filling out fields in a set of computer forms [0006 of page 1; 0016 of page 2; ab];

storing the clinical trial parameters in a central database [user membership database, 100 of fig. 4];

entering subject enrollment data corresponding to at least one clinical trial defined by the clinical trial parameters via an Internet web portal [see fig. 1, 5, 7; 0017-0020 of page 2];

storing the subject enrollment data in the central database substantially as it is entered in time0063-0066, 0076 of page 5];

generating a chart displaying selected data aggregated from the subject enrollment data to graphically portray subject enrollment attributes pertaining to a selected clinical trail from among said at least one clinical trial [records in charts, 0100 of page 7].

However, Thangaraj does not explicitly teach enabling clinical trial site personnel to enter subject enrollment data. De Vries teaches enabling clinical trial site personnel to enter subject enrollment data [the trial investigator collects and maintains data 0012-0018 of pages 1-2].

Therefore, it would have been obvious to one of ordinary skill in the Data Processing art at the time of the invention to add the feature of De Vries to the Thangaraj's system as an essential means to assure collecting data in a secure fashion and maintaining the trial participants' safety and privacy within a standard of ethics acceptance for human experimentation.

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As to claim 2, Thangaraj and De Vries teach the invention substantially as claimed. Thangaraj further teaches that the selected data are aggregated across an entire protocol corresponding to the selected clinical trial [0019 of page 2].

As to claim 3, Thangaraj and De Vries teach teaches the invention substantially as claimed. Thangaraj further teaches that the selected data correspond to an individual site that implements a protocol corresponding to a clinical trial [0077 of pages 5-6].

As to claim 4, Thangaraj and De Vries teach the invention substantially as claimed. De Vries further teaches that the administrator is enabled to define regions corresponding to a clinical trial protocol, each region corresponding to one or more sites that perform subject tests defined by a clinical trial protocol, and the selected data are aggregated across a selected region [0073-0081 of page 5].

As to claim 5, Thangaraj and De Vries teach the invention substantially as claimed. De Vries further teaches that the chart comprises an enrollment rate analysis chart that portrays a number of subjects newly enrolled for the selected clinical trial during each of a plurality of periodic intervals using a selected aggregation level [0083-0084 of page 5; 0123-0124 of page 8].

As to claim 6, Thangaraj and De Vries teach the invention substantially as claimed. De Vries further teaches that the selected aggregation level corresponds to one of a site, a region

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comprising a plurality of sites, or a protocol comprising all of the sites used to perform a protocol corresponding to the selected clinical trial [0070-0083 of page 5].

As to claim 7, Thangaraj and De Vries teach Thangaraj teaches the invention substantially as claimed. De Vries further teaches a plurality of subject status totals pertaining to the selected clinical trial and corresponding to a selected aggregation level [0083 of page 5].

As to claim 8, Thangaraj and De Vries teach Thangaraj teaches the invention substantially as claimed. De Vries further teaches that the selected aggregation level corresponds to one of a site, a region comprising a plurality of sites, or a protocol comprising all of the sites used to perform a protocol corresponding to the selected clinical trial [0073-0081 of page 5].

As to claim 9, Thangaraj and De Vries teach the invention substantially as claimed. De Vries further teaches that the administrator is enabled to define said plurality of clinical trial parameters using a computer that has a dedicated connection to the central database [0068-0080 of page 5].

As to claim 10, Thangaraj and De Vries teach the invention substantially as claimed. Thangaraj further teaches that the administrator is enabled to define said plurality of clinical trial parameters using a computer that stores corresponding data in a local database, further comprising synchronizing the local database with the central database such that data pertaining to said plurality of clinical trial parameters are copied to the central database [0115 of page 8].

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As to claim 11, Thangaraj and De Vries teach the invention substantially as claimed. De Vries further teaches the computer forms generated by rendering applets on a browser [fig. 9-10].

As to claim 12, Thangaraj and De Vries teach the invention substantially as claimed. Thangaraj further teaches that the Internet web portal is supported by an application server hosting a plurality of software modules, including an object manager that interacts with a web engine to generate web-based forms including a plurality of fields that enable users of the Internet web portal to enter the subject enrollment data corresponding to said at least one clinical trial and a data manager that interacts with the object manager and a database server that hosts the central database to store data corresponding to the plurality of fields in the web-based forms [fig. 7; 0117-0120 of pages 8-9].

As to claim 13, Thangaraj and De Vries teach the invention substantially as claimed. Thangaraj further teaches that the object manager includes a plurality of object classes and wherein the web-based forms comprise java-script based applets corresponding to a set of java-script object classes that substantially mirror respective object classes corresponding to the object manager 0072 of page 5; 0111 of page 8].

As to claims 15-24, all limitations of these claims have been addressed in the analysis of claims 1-14 above, and these claims are rejected on that basis.

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and/or:

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thuy Pardo, whose telephone number is (703) 305-1091. The examiner can normally be reached Monday through Thursday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dov Popovici, can be reached at (703) 305-3830.

The fax phone number for the organization where this application or proceeding is assigned are as follows: (703) 872-9306 (Official Communication)

(703) 746-5616 (Use this Fax#, only after approval by Examiner, for "INFORMAL" or "Draft" communication. Examiner may request that a formal/amendment

Any inquiry of a general nature of relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 305-3900.

5. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington, D.C. 20231

or faxed to:

be faxed directly to then on occasions).

(703) 308-9051, (for formal communications intended for entry)

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Or:

(703) 308-5359, (for informal or draft communications, please label "PROPOSED" or "DRAFT")

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington. VA., Sixth Floor (Receptionist).

August 09, 2004

THUY N. PARDO PRIMARY EXAMINER